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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,051	04/26/2001	Martin T. Gerber	P0008436.03	8909
64619	7590	01/09/2008		
CAMPBELL NELSON WHIPPS, LLC			EXAMINER	
408 ST. PETER STREET			EVANISKO, GEORGE ROBERT	
SUITE 240				
ST. PAUL, MN 55102			ART UNIT	PAPER NUMBER
			3762	
			MAIL DATE	DELIVERY MODE
			01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/843,051

Applicant(s)

GERBER ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38 and 40-70 is/are pending in the application.
- 4a) Of the above claim(s) 51-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 40-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/07 has been entered.

Election/Restrictions

Newly submitted claims 51-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed could be used for a different method not for the sacral area but for the heart.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 40-43, 46, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann et al (5534022). Hoffmann shows in figure 13 the use of a distal ring electrode, 38, coil electrode, 20, proximal ring electrode, 36, and another proximal ring electrode as element 20'. Hoffmann also shows the use of electrode connector, e.g. 27/26/29, in figures 4, 5, or 7 and incorporates by reference 08/018832 (patent 5385578) to describe how the electrode is welded/adhered/connected to the conductor. In addition, Hoffman is capable of meeting the functional use recitations presented in the claims of being used for insertion through the sacrum into position for stimulation of one or more sacral nerves without causing damage since Hoffmann's lead is of a similar size (about 2.5 mm) and shape as the applicants lead and Hoffmann's lead is very flexible and used in the veins and the heart (e.g. figures 9, 10, column 3, etc.). Hoffmann's coil electrode, 20, includes a wire coil since it is a "coil" electrode that is made of wire coils (e.g. col. 6). Finally, Hoffman's electrodes are solid surface material electrodes since they are neither gas or liquid, but made from materials having a solid surface, such as the flat or round wires. It is noted that the claims do not state that the entire ring electrode is a solid surface and it is noted that Hoffman uses "solid" surface materials (dictionary definition of solid-- of uniformly close and coherent texture : COMPACT b: possessing or characterized by the properties of a solid : neither gaseous nor liquid).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 45 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffmann.

Hoffman discloses the claimed invention having a diameter of "about 2.5 mm" which meets the limitation of the applicants claim language of "about 2 mm" and shows in figures 4, 5, 7 and 8 and describes in the incorporated reference, 08/018832, how the electrode is welded to the electrode connector as a butt weld.

In the alternative, Hoffmann discloses the claim invention except for the diameter of the coil being about 0.5 to about 2 mm and the connector being butt-welded to the electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Hoffmann, with the diameter of the coil being

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about 0.5 to about 2 mm and the connector being butt-welded to the electrode since it was known in the art that implantable leads use: the diameter of the coil being about 0.5 to about 2 mm to provide the predictable results of an implantable lead that is small, unobtrusive, and does not interfere with the bodies functions; and the connector being butt-welded to the electrode to provide the predictable results of a secure, reliable, and easily produced connection to connect two elements.

In addition, for the claimed 0.5-2 mm range, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05

Claims 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann.

Hoffman discloses the claimed invention except for the length of the coil electrode to be 0.1 to 1.5 inches and the first and second ring electrode to be platinum, platinum-iridium, or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by Hoffmann, with the length of the coil electrode to be 0.1 to 1.5 inches and the first and second ring electrode to be platinum, platinum-iridium, or stainless steel since it was known in the art that coil electrodes are provided in the length of 0.1 to 1.5 inches to provide the predictable results of allowing the coil electrode

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to be placed near the area that needs stimulation without needing the precise placement of a point electrode and/or to provide the appropriate stimulation field to effectively stimulate a particular area of the body and since it was known in the art that ring electrodes are made from platinum, platinum-iridium, or stainless steel to provide the predictable results of a conventional biocompatible electrode that effectively stimulates and/or senses in the body.

Response to Arguments

Applicant's arguments filed 10/16/07 have been fully considered but they are not persuasive. The argument that the metal wire of Hoffman is not a solid surface material is not persuasive since the metal wire is/has a material that is a solid surface.

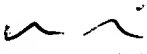
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

12/30/7

GRE
12/30/07